| | Application No. | Applicant(s) |
|---|---|---|
| | Approacion No. | Apprount(5) |
| Notice of Allowability | 10/521,367 | BAKHIT ET AL. |
| | Examiner | Art Unit |
| | GiGi Huang | 1609 |
| The MAILING DATE of this communication appeal All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSED in this ap or other appropriate communication IGHTS. This application is subject to | plication. If not included will be mailed in due course. THIS |
| 1. This communication is responsive to examiner's amendment | ent requested on 4/12/2007. | |
| 2. The allowed claim(s) is/are <u>1-11,23,24 and 28</u> . | | |
| 3. ☐ Acknowledgment is made of a claim for foreign priority unallocation of the: a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have | e been received. | |
| 2. Certified copies of the priority documents have | · · · · · · · · · · · · · · · · · · · | |
| 3. Copies of the certified copies of the priority do | cuments have been received in this | national stage application from the |
| International Bureau (PCT Rule 17.2(a)). * Certified copies not received: | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be subminformal PATENT APPLICATION (PTO-152) which give | MENT of this application. itted. Note the attached EXAMINER | 'S AMENDMENT or NOTICE OF |
| 5. CORRECTED DRAWINGS (as "replacement sheets") must | | dun is denoterit. |
| (a) ☐ including changes required by the Notice of Draftspers | son's Patent Drawing Review (PTO- | 948) attached |
| 1) 🗌 hereto or 2) 🔲 to Paper No./Mail Date | | |
| (b) ☐ including changes required by the attached Examiner's Paper No./Mail Date | s Amendment / Comment or in the C | Office action of |
| Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t | | |
| DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT | sit of BIOLOGICAL MATERIAL r FOR THE DEPOSIT OF BIOLOGIC | nust be submitted. Note the AL MATERIAL. |
| | | |
| Attachment(s) | E | lotont Amelication |
| Notice of References Cited (PTO-892) Dotice of Draftperson's Patent Drawing Review (PTO-948) | 5. ☐ Notice of Informal F6. ☐ Interview Summary | • • |
| | Paper No./Mail Da | te |
| Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 6/20/2005 | 7. 🛛 Examiner's Amendr | ment/Comment |
| Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. ☑ Examiner's Statement 9. ☐ Other | ent of Reasons for Allowance |
| | | GiGi Huang Patent examiner Art unit 1609 |

Application/Control Number: 10/521,367

Art Unit: 1609

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Brent Johnson on 4/12/07.

- 2. The application has been amended as follows:
 - a. Rewrite the claim 1 as following:
- ---- 1. (Currently amended) A dosage form comprising a prostamide and a trefoil factor family peptide wherein the prostamide is bimatoprost and the peptide is selected form the group consisting of TFF1 and TFF3. ---
 - b. In claim 2, line 2; delete [prostaglandin of] right before "prostamide".
 - c. Cancel claims 12-13, 22, and 25-27.
 - d. Cancel non-elected claims 14-21.
 - e. In claim 23, line 1, insert ----further---- right after "which".
 - f. Rewrite the claim 28 as following:
- ---- 28. (Currently amended) A pharmaceutical composition for treatment of glaucoma comprising a composition comprising a therapeutically effective amount of prostamide and a therapeutically effective amount of trefoil factor family

Page 2

Art Unit: 1609

peptide wherein the prostamide is bimatoprost and the peptide is selected from the group consisting of TFF1 and TFF3. ----

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance. Tan et al. (2000, Prostanoids mediate...) teaches the combination of trefoil factor with carbacyclin (an analogue of prostaglandin I2 and/or prostaglandin E2) for reduction of cell injury to the gastrointestinal mucosa. However, it fails to teach the use of bimatoprost as part of a composition with the trefoil factor family peptide, nor for the use in glaucoma. Thus the claimed invention is novel and patentably distinct over the prior art of the record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee, and to avoid delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on the Statement of Reasons for Allowance".

Conclusion

- 4. All the pending claims 1-11, 23-24, and 28 are allowed.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562 or Vickie Kim (Primary

Application/Control Number: 10/521,367

Art Unit: 1609

Paten Examiner) at 571-272-0616. The fax phone number for the organization where

Page 4

this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH